## REMARKS

In the present amendment, claims 1, 2, 3, 4, 12, 17, 18 and 23 have been amended and new claims 27 and 28 have been added. Accordingly, claims 1-6, 9-19, and 22-28 are pending in the application with claims 1, 12, 17 and 23 being independent. Of the pending claims, claims 1, 2, 5, 6, 9, 10, 13, 17-19, 22, 25-28 are under consideration and claims 3, 4, 11-13, 15, 16, 23, and 24 have been withdrawn from consideration.

Applicants note that claims 1 and 17 have been amended to recite that "the fine bone powder comprises sub-micron particles." Support for the amendments can be found in the present specification, e.g., at page 14, lines 5-7.

Furthermore, claims 2 and 18 have been amended to overcome the indefiniteness rejection under 35 U.S.C. § 112, second paragraph, by adding the term "pores," as also suggested by the Examiner. Also, withdrawn claims 3, 4, 12, and 23 have been amended to comply with the language of amended claims 1, 2, 17, and 18, respectively.

New dependent claims 27 and 28 have been added to recite the feature that the "fine bone powder is provided from autologous bone." Support for new claims 27 and 28 can be found in the present specification, e.g., at page 13, lines 3-12.

No new matter has been added.

**Response to Restriction Requirement**

The Office Action states that the Restriction Requirement mailed on August 27, 2009 "was not set forth properly as Group I and Group II do share a common technical feature of a porous structure impregnated with bone powder." However, the Office Action refers to U.S. Patent No. 4,430,760 to Smestad et al., hereinafter "Smestad," which is also cited in the 102(b) rejection of the present Office Action (see discussion below), asserting that Smestad discloses a porous structure impregnated with bone

powder. The Office Action therefore concludes that no unity of invention exist between Group I and Group II because the corresponding technical features allegedly do not define a contribution over the cited art. Applicants submit that the Office will be required to withdraw the Restriction Requirement when the claims at issue recite subject matter that is not disclosed in the art. Applicants further note that Smestad is discussed below, with regard to the rejection under 35 U.S.C. § 102(b). This discussion is incorporated by reference herein.

The Office Action withdraws claims 9 and 22 from the species restriction, stating that these claims "were improperly set forth as belonging to species A."

In summary, the Office Action concludes that claims 3, 4, 11, 13, 15, 16, 23, and 24 are withdrawn from further consideration as allegedly being "drawn to a nonelected Group, species, and subspecies, there being no allowable generic or linking claim."

Applicants respectfully disagree with the withdrawal of at least claims 3 and 4 from further consideration. Applicants note that claims 3 and 4 both employ the elected species "fine communicating pores open to an outer surface of a porous structure." Moreover, claims 3 and 4 are not limited to the species "structure porous only at the surface layer." The Examiner is respectfully requested to explain why claims 3 and 4 have been withdrawn from further consideration.

Applicants further note that claims 3, 4, 11, 13, 15, 16, 23, and 24 remain pending, subject to possible rejoinder.

**Rejection under 35 U.S.C. § 112, second paragraph**

The Office Action rejects claims 2 and 18 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The Action asserts that the limitation "1 or

more" is unclear. In response, Applicants note that claims 2 and 18 have been amended to recite "1 or more pores," as also suggested by the Examiner. Accordingly, withdrawal of the indefiniteness rejections is respectfully requested.

**Rejection under 35 U.S.C. § 102(b)**

The Office Action rejects claims 1, 5, 6, 9, 10, 14, 17, 19, 22, and 25-26 under 35 U.S.C. § 102(b) as allegedly being anticipated by Smestad (US 4,430,760).

Applicants respectfully traverse the rejection. Applicants note that in an attempt to advance prosecution of the present application, and without expressing agreement with or acquiescence to the rejection, independent claims 1 and 17 have been amended to even more clearly distinguish the present claims from Smestad, i.e., by reciting that "the fine bone powder comprises sub-micron particles."

Applicants point out that Smestad is directed to a bone prosthesis comprising demineralized bone or dentin powder or mixtures thereof contained in a biocompatible porous casing. The porous casing may be, e.g., a pouch or a container made from fabrics or microporous membranes. Smestad teaches that examples of woven fabrics are Dacron, nylon and carbon fabrics; while examples for nonwoven fabrics are collagen, polyesters, polyamides or polyolefins. Further, Smestad teaches that the microporous membranes are made by forming pores by well-known pore-forming techniques in various kinds of dense polymers, such as polycarbonates, polyamides, polyesters, polyolefins, polysaccharides, and cellulosics. With respect to the demineralized bone powder, Smestad discloses that demineralized bone is made by contacting bone with acid such as hydrochloric acid, and that the obtained demineralized bone powder has a particle size in the range of about 40 to 500 μm, preferably, 75 to 250 μm (see Smestad, column 2, lines 23-27).

In contrast to Smestad, Applicants note that the presently claimed invention employs the use of bone powder obtained by pulverization of living bones and does not perform a demineralization process. Applicants emphasize that living bone contains a lot of apatite of regular arrangement and proteins such as collagen, bone morphogenetic protein (BMP), etc. BMP being supported on the regular-arranged apatite is a protein contributing to the formation of bone. Applicants note that demineralized bone obtained by the treatment with acids, like hydrochloric acid, comprises mainly protein such as collagen, but does not contain apatite (anymore). Thus, in the demineralized bone powder used in the bone prosthesis disclosed in Smestad, also BMP supported on the regular-arranged apatite may be partly washed out together with the apatite by treatment with the acid. On the other hand, fine bone powder obtained by pulverizing living bones, as employed in the presently claimed invention, contains apatite together with collagen and BMP. Thus bone powder of living bones can strongly support the bone-inducing capability and is capable of regenerating a large amount of bone (several tens of times) from a small amount of bone. Particularly, as also taught in the present specification, the use of autologous bones "is considered best to regenerate bone" with high capacity (see, e.g., specification, paragraph [0002]). Applicants note that Smestad does not teach or suggests the use of living bones and requires demineraliziation of the bone sourse. Accordingly, it appears that Smestad has little appreciation of the bone-inducing capability of living bones.

Applicants further note that the fine bone powder of the presently claimed invention comprises sub-micron particles, while Smestad discloses for the demineralized bone powder a particle-size in the range of about 40 to 500 μm. The sub-micron particles of the fine bone powder of the present invention are distributed widely in the fine

communicating pores or recesses of the biocompatible matrix, and are capable of inducing spontaneous formation of bone (see also, e.g., paragraph [0040], [0054] or [0062] of the published application). Accordingly, the sub-micron particles contained in the bone-powder-impregnated matrix of the present invention have an important function to support a high bone-forming capability of the claimed material.

Moreover, Applicants emphasize that Smestad teaches a casing that surrounds and holds the demineralized bone powder in a specific shape, and the pores of the casing in Smestad are required to be smaller than the smallest particles of the demineralized bone powder. For example, Smestad teaches at column 3, lines 19-33:

> The maximum pore size will be less than the minimum particle size of the demineralized bone of dentin powder. Accordingly, for embodiments having particle size down to 40 microns, the maximum pore size will be below 40 microns. ... Preferably, it is about 10-15 microns below the minimum particle size of the demineralized bone or dentin powder.

In comparison to Smestad, the present claims recite that a porous matrix is impregnated with fine bone powder. As specifically taught in the present specification, for efficient bone formation it is required that sub-micron particles are able to enter the fine pores of the matrix. This is a completely different approach from that taught in Smestad, who intends to exclude passing of small demineralized bone powder particles through the pores of the casing by selecting much bigger particles than the pore size of the casing. Accordingly, because the bone prosthesis described in Smestad contains demineralized powder within the interior of a porous closed container, the pores of which are smaller than the particles size of the demineralized bone powder, the demineralized bone powder cannot contact with surrounding living bone. On the other hand, because the bone-powder-impregnated, porous structure of the present invention comprises a

porous matrix impregnated with fine powder, wherein the pores are open on the entire outer surface of the porous structure, the bone powder can contact with surrounding living bone and help bone-inducing capability efficiently. Accordingly, the bone prosthesis disclosed in Smestad is not comparable in the structure and effect with the material of the presently claimed invention. Smestad neither discloses nor suggests bone-powder-impregnated structures comprising a porous or a surface-roughened matrix impregnated with the fine bone powder comprising sub-micron particles by pulverizing living bones.

In view of the foregoing discussion and the amendments to the claims, since Smestad does not teach or suggest several features of the presently claimed invention, withdrawal of the anticipation rejection is respectfully requested.

**Rejection under 35 U.S.C. § 103(a)**

The Office Action rejects claims 2 and 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Smestad and further in view of Smith et al. (US 2004/0253279), hereinafter "Smith."

Applicants note that the rejection is based on the assumption that claims 1 and 17 are anticipated by Smestad. For the reasons discussed above, Applicants note that Smestad fails to disclose or suggest all elements of the present claims 1 and 17. Applicants note that Smith fails to disclose the deficiency of Smestad with respect to claims 1 and 17. Moreover, Applicants note that Smith merely discloses a porous article having a porosity of 20% to 95% and comprising cell wall and struts defining pores of sizes in the range of 15 to 150 microns, see Smith, paragraph [0023]. Accordingly, Smith neither discloses nor suggests fine communicating pores being open on an outer surface

of the porous structure at a density of 1 or more pores per an area of 50 μm x 50 μm, as employed by the present claims 2 and 18.

Accordingly, because the combination of Smestad and Smith does not lead to or suggest the features of claims 2 and 18, withdrawal of the obviousness rejection is respectfully requested as well.

Respectfully submitted,
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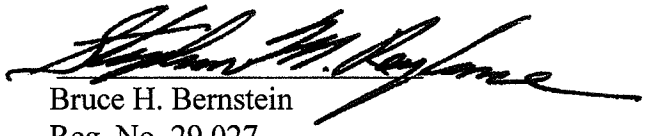

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April 16, 2010
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